

NMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier G. Prusky

Food and Drug Administration

[Docket No. 01D-0368]

Draft Guidance for Industry on Submitting Marketing Applications According to the ICH/CTD Format; General Considerations; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until *[insert date 60 days after date of publication in the **Federal Register**]*, the comment period for the draft guidance for industry entitled "Submitting Marketing Applications According to the ICH/CTD Format; General Considerations" that appeared in the **Federal Register** of September 5, 2001 (66 FR 46464). The agency is taking this action in response to several informal requests for an extension of the comment period.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the **Federal Register**]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3844, FAX 888-cb0326

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CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20857, 301–594–5400; or Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

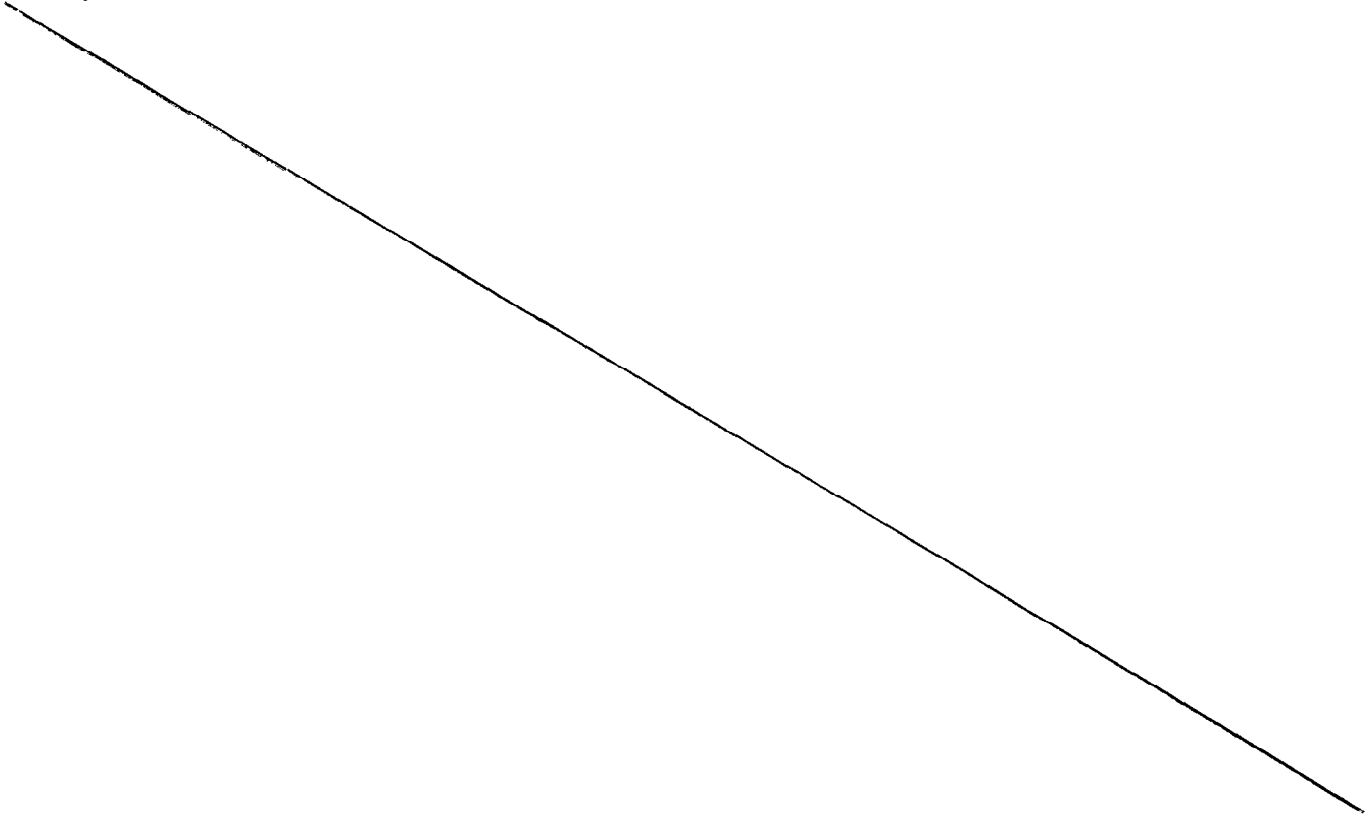
I. Background

In the **Federal Register** of September 5, 2001 (66 FR 46464), FDA published a notice announcing the availability of a draft guidance for industry entitled “Submitting Marketing Applications According to the ICH/CTD Format; General Considerations.” This guidance provides information on how to organize new drug applications, abbreviated new drug applications, and biologics license applications based on the International Conference on Harmonization M4 guidance on organizing the Common Technical Document for the registration of pharmaceuticals for human use. Interested persons were given until November 5, 2001, to submit written or electronic comments on the draft guidance. In response to several informal requests from drug and biologic manufacturers, FDA has decided to reopen the comment period on the draft guidance until *[insert date 60 days after date of publication in the*

Federal Register], to allow interested persons additional time to submit comments.

II. Comments

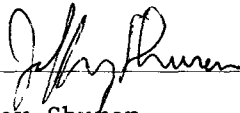
Interested persons may, on or before [*insert date 60 days after date of publication in the Federal Register*], submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 4/8/03
April 8, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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